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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,097	11/04/2005	Ralf-Christian Schlothauer	14923.0024	7026

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STEPTOE & JOHNSON LLP
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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/521,097	SCHLOTHAUER ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7-9,13-22,24,26-29,32-34 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-9,13-22,24,26-29,32-34 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on September 12, 2008 is acknowledged. Claims 1, 7, 13, 15, 17-22, 24, 26-29, and 32-34 have been amended. Claims 4-6, 10-12, 23, 25, 30, 31 and 35-43 have been canceled. Claims 44-47 have been added. Claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 are pending and under consideration.

Objections Withdrawn

1. In view of Applicant's amendment, the objection to the specification for the use of the trademarks Dionex, CMD and Glucidex on pages 44 and 51 is withdrawn.

2. In view of Applicant's amendment, the objection of claims 24, 26, 33 and 34 for reciting non-elected inventions is withdrawn.

Rejections Withdrawn

3. In view of Applicant's argument, the rejection of claims 1-9, 15-22, 24, 26-29 and 32-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

4. In view of Applicant's amendment, the rejection of claims 1, 2, 4-6, 15-21, 24, 26, 27, 29 and 32-34 under 35 U.S.C. 102(b) as being anticipated by Van Den Berg et al.

(WO 94/12656) is withdrawn. The cancellation of claims 4-6 renders the rejection of said claims moot.

5. In view of Applicant's amendment, the rejection of claims 1-4, 15-20, 24, 26 and 32 under 35 U.S.C. 102(b) as being anticipated by Geel-Schutten et al. (Appl Microbiol Biotechnol, 1998; 50: 697-703) is withdrawn. The cancellation of claim 4 renders the rejection of said claim moot.

6. In view of Applicant's amendment, the rejection of claims 1-9, 15-22, 24, 26-29 and 32-34 under 35 U.S.C. 103(a) as being unpatentable over Geel-Schutten et al. (Appl Microbiol Biotechnol, 1998; 50: 697-703) and Van Den Berg et al. (WO 94/12656) is withdrawn. The cancellation of claims 4-6 renders the rejection of said claim moot.

Rejections Maintained

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. The rejection of claims 1, 3, 7-9, 15-17 and 19-20 which is directed to non-statutory subject matter and reads on a product of nature is maintained for the reasons set forth in the previous Office action. The cancellation of claims 4-6 renders the rejection of said claims moot.

Applicant argues that:

1) Claim 1 has been amended to include the phrase "wherein the microorganism is *Lactobacillus sakei* strain 570".

Applicant's arguments have been considered and are deemed non-persuasive.

With regard to Point 1, while Applicant has amended the claim, the organism still reads on a product of nature. It is suggested that Applicant amend the claim to the following: "An isolated viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570".

As previously presented, in the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme".

New Grounds of Objection/Rejection

Claim Objections

8. Claim 1 is objected to because of the following informalities: claim 1 recites in part, comprising an viable lactic acid microorganism. This is grammatically incorrect and appropriate correction is required.

9. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 does not further limit claim 1.

10. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 does not further limit claim 1 because by definition an EPS is a polysaccharide.

11. Applicant is advised that should claim 24 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejected claims are drawn to a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570.

The claims are drawn to a vast genus of enzymes synthesized by said microorganism and an exopolysaccharide (EPS) produced by said enzyme. The specification is equally silent with regard to which EPS is capable of being modulated (see claim 15) and which EPS has the ability to improve the texture, body, mouth feel, viscosity, structure and/or organoleptic properties of a food containing said EPS as an ingredient (see claim 17). Further, the specification is silent with regard to which EPS

has the capacity to reduce the production of gas by the gastrointestinal microorganism when used as ingredients to products for consumption.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of the claimed antigenic outer membrane protein or an immunogenic fragment thereof, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of enzymes and EPS, the skilled artisan could not immediately recognize or distinguish members of the claimed genus. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of a composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570 is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejected claims are drawn to a composition comprising a composition for consumption, said composition comprising a viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide (EPS) product of said enzyme; wherein said microorganism is *Lactobacillus sakei* strain 570.

Because it is not clear that cell lines possessing the properties of ***Lactobacillus sakei* strain 570** are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above ***Lactobacillus sakei* strain 570**, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority

under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
>
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
>
> (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As well as a statement that removes restrictions to provide access to this strain upon granting of a patent has not made, either in the instant Specification, nor in Applicant's Remarks.

One of the critical conditions of Deposit is defined in 37 CFR 1.808 requires that the deposit of biological material be made under two conditions: (A) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and (B) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological

material be irrevocably removed upon the granting of the patent. Upon making this statement, the rejection under 35 USC 112, first paragraph will be withdrawn. This rejection can be obviated through perfection of the Deposit and amendment of the claims to clearly set forth the Deposited strains.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the ***Lactobacillus sakei* strain 570** described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-3, 7-9, 13-22, 24, 26-29, 32-34 and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the phrase "comprising an viable lactic acid microorganism, an enzyme synthesized by said microorganism and an exopolysaccharide produce of said enzyme". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. It is unclear why the composition comprises a) viable lactic acid microorganism, b) an enzyme synthesized by said microorganism and c) an exopolysaccharide product of said enzyme. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 21 is rendered vague and indefinite by the use of the terms "concentrated form". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes a "concentrated form"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 24 is rendered vague and indefinite by the use of the term "component". It is unclear what is meant by said term, as it is not explicitly defined in the specification. What constitutes a "component"? What core features/structures must be maintained? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 29 is rendered vague and indefinite by the use of the terms "functional food". It is unclear what is meant by said terms, as it is not explicitly defined in the specification. What constitutes a "functional food"? As written, it is to determine the metes and bounds of the claimed invention.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LJT
1/5/09

/Robert A. Zeman/
for Lakia J. Tongue, Examiner of Art Unit 1645